



US009314298B2

(12) **United States Patent**
Christian et al.

(10) **Patent No.:** **US 9,314,298 B2**
(45) **Date of Patent:** **Apr. 19, 2016**

(54) **VACUUM-STABILIZED ABLATION SYSTEM**

(56) **References Cited**

(75) Inventors: **Steven C. Christian**, New Brighton, MN (US); **John P. Goetz**, Aptos, CA (US); **Thomas B. Eby**, Mountain View, CA (US)

U.S. PATENT DOCUMENTS

984,756 A 2/1911 Frisch
3,369,550 A 2/1968 Armao et al.

(Continued)

(73) Assignee: **St. Jude Medical, Atrial Fibrillation Divisions, Inc.**, St. Paul, MN (US)

FOREIGN PATENT DOCUMENTS

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1290 days.

WO WO-97/29699 8/1997
WO WO-97/38748 10/1997

(Continued)

(21) Appl. No.: **13/150,380**

OTHER PUBLICATIONS

(22) Filed: **Jun. 1, 2011**

Supplementary European Search Report, EP03759515.4-1265, Publication Date: Nov. 8, 2010.

(65) **Prior Publication Data**

US 2011/0230799 A1 Sep. 22, 2011

(Continued)

Related U.S. Application Data

Primary Examiner — Emily Schmidt

(63) Continuation-in-part of application No. 12/408,632, filed on Mar. 20, 2009, now Pat. No. 8,597,288.

(74) *Attorney, Agent, or Firm* — Wiley Rein LLP

(60) Provisional application No. 61/101,972, filed on Oct. 1, 2008.

(57) **ABSTRACT**

(51) **Int. Cl.**

A61B 18/18 (2006.01)

A61B 18/14 (2006.01)

A61N 7/02 (2006.01)

(Continued)

A tissue ablation apparatus includes a body having at least two lumens extending therethrough and an ultrasound ablation element positioned within a distal region of the body. The ultrasound ablation element includes an ultrasound transducer and a membrane. One of the lumens is arranged so as to deliver a fluid into a cavity defined between the transducer and the membrane. A first orifice is provided in the body proximal of the ultrasound ablation element and is open to the first lumen to define a first vacuum pathway. A distal vacuum chamber, opening to a second orifice in the body, is defined by the body distal of the ultrasound ablation element and is in communication with the first lumen to define a second vacuum pathway. At least one flow control apparatus is provided to regulate flow through one of the vacuum pathways independent of flow through the other vacuum pathway.

(52) **U.S. Cl.**

CPC **A61B 18/1492** (2013.01); **A61N 7/022** (2013.01); **A61B 5/042** (2013.01); **A61B 5/053** (2013.01); **A61B 2017/003** (2013.01); **A61B 2018/00291** (2013.01);

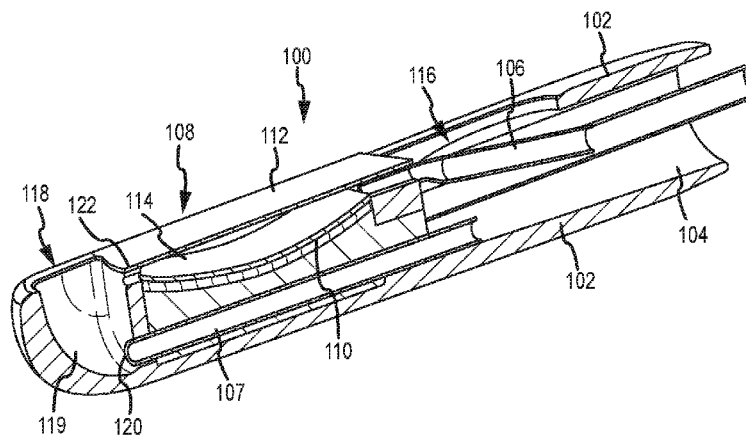
(Continued)

(58) **Field of Classification Search**

CPC **A61B 2018/00291**; **A61B 2017/308**; **A61N 7/02**

See application file for complete search history.

20 Claims, 13 Drawing Sheets



(51)	Int. Cl.		5,722,402 A	3/1998	Swanson et al.
	<i>A61B 5/042</i>	(2006.01)	5,722,403 A	3/1998	McGee et al.
	<i>A61B 5/053</i>	(2006.01)	5,728,094 A	3/1998	Edwards et al.
	<i>A61B 17/00</i>	(2006.01)	5,733,280 A	3/1998	Avitall
	<i>A61B 18/00</i>	(2006.01)	5,735,280 A	4/1998	Sherman et al.
(52)	U.S. Cl.		5,746,224 A	5/1998	Edwards et al.
	CPC	<i>A61B 2018/00363</i> (2013.01); <i>A61B 2018/00577</i> (2013.01); <i>A61B 2218/002</i> (2013.01)	5,776,176 A	7/1998	Rudie
			5,782,828 A	7/1998	Chen et al.
			5,782,899 A	7/1998	Imran
			5,785,706 A	7/1998	Bednarek
			5,797,960 A	8/1998	Stevens et al.
			5,800,484 A	9/1998	Gough
			5,810,721 A	9/1998	Mueller et al.
			5,817,021 A	10/1998	Reichenberger
			5,823,197 A	10/1998	Edwards
			5,827,281 A	10/1998	Levin
			5,830,214 A	11/1998	Flom et al.
			5,846,218 A	12/1998	Briskin
			5,849,028 A	12/1998	Chen
			5,860,951 A	1/1999	Eggers et al.
(56)	References Cited		5,860,974 A	1/1999	Abele
	U.S. PATENT DOCUMENTS		5,861,021 A	1/1999	Thome
	4,022,215 A	5/1977 Benson	5,863,291 A	1/1999	Schaer
	4,072,152 A	2/1978 Linehan	5,871,449 A	2/1999	Brown
	4,207,874 A	6/1980 Choy	5,885,278 A	3/1999	Fleischman
	4,353,371 A	10/1982 Cosman	5,891,134 A	4/1999	Goble et al.
	4,375,818 A	3/1983 Suwaki et al.	5,899,898 A	5/1999	Arless
	4,655,216 A	4/1987 Tischer	5,899,899 A	5/1999	Arless
	4,786,155 A	11/1988 Fantone et al.	5,916,213 A	6/1999	Haissaguerre
	4,836,191 A	6/1989 Noske	5,971,983 A	10/1999	Lesh
	4,889,137 A	12/1989 Kolobow	6,004,269 A	12/1999	Crowley et al.
	4,924,863 A	5/1990 Sterzer	6,012,457 A	1/2000	Lesh
	4,957,099 A	9/1990 Hassler	6,023,638 A	2/2000	Swanson
	4,976,711 A	12/1990 Parins	6,030,379 A	2/2000	Panescu
	4,985,030 A	1/1991 Melzer et al.	6,059,778 A	5/2000	Sherman
	5,000,185 A	3/1991 Yock	6,068,629 A	5/2000	Haissaguerre et al.
	5,013,312 A	5/1991 Parins et al.	6,071,274 A	6/2000	Thompson et al.
	5,014,750 A	5/1991 Winchell	6,071,279 A	6/2000	Whayne et al.
	5,073,154 A	12/1991 Ivey	6,071,282 A	6/2000	Fleischman
	5,109,830 A	5/1992 Cho	6,117,101 A	9/2000	Diederich
	5,190,541 A	3/1993 Abele et al.	6,120,496 A	9/2000	Whayne et al.
	5,197,964 A	3/1993 Parins	6,120,500 A	9/2000	Bednarek
	5,263,493 A	11/1993 Avitall	6,139,492 A	10/2000	Vierra
	5,290,286 A	3/1994 Parins	6,139,563 A	10/2000	Cosgrove et al.
	5,295,484 A	3/1994 Marcus et al.	6,142,994 A	11/2000	Swanson et al.
	5,341,807 A	8/1994 Nardella	6,146,379 A	11/2000	Fleischman et al.
	5,366,443 A	11/1994 Eggers et al.	6,152,920 A	11/2000	Thompson et al.
	5,370,675 A	12/1994 Edwards et al.	6,161,543 A	12/2000	Cox et al.
	5,385,148 A	1/1995 Lesh	6,164,283 A	12/2000	Lesh
	5,406,946 A	4/1995 Imran	6,171,303 B1	1/2001	Ben-Haim et al.
	5,409,483 A	4/1995 Campbell	6,206,831 B1	3/2001	Suorsa et al.
	5,423,807 A	6/1995 Milder	6,212,426 B1	4/2001	Swanson et al.
	5,427,119 A	6/1995 Swartz et al.	6,214,754 B1	4/2001	Stein
	5,437,664 A	8/1995 Cohen et al.	6,217,528 B1	4/2001	Koblish et al.
	5,443,463 A	8/1995 Stern et al.	6,237,605 B1	5/2001	Vaska et al.
	5,449,348 A	9/1995 Dryden	6,238,393 B1	5/2001	Mulier et al.
	5,452,733 A	9/1995 Serman et al.	6,241,722 B1	6/2001	Dobak et al.
	5,462,521 A	10/1995 Brucker et al.	6,241,727 B1	6/2001	Tu
	5,462,545 A	10/1995 Wang et al.	6,254,600 B1	7/2001	Willink et al.
	5,472,441 A	12/1995 Edwards et al.	6,270,476 B1	8/2001	Santoian
	5,497,774 A	3/1996 Swartz et al.	6,302,880 B1	10/2001	Schaer
	5,501,655 A	3/1996 Rolt	6,311,692 B1	11/2001	Vaska et al.
	5,501,698 A	3/1996 Roth et al.	6,314,962 B1	11/2001	Vaska et al.
	5,505,730 A	4/1996 Edwards	6,314,963 B1	11/2001	Vaska et al.
	5,540,679 A	7/1996 Fram et al.	6,325,797 B1	12/2001	Stewart et al.
	5,540,681 A	7/1996 Strul et al.	6,325,798 B1	12/2001	Edwards et al.
	5,553,612 A	9/1996 Lundback	6,361,531 B1	3/2002	Hissong
	5,555,883 A	9/1996 Avitall	6,364,876 B1	4/2002	Erb
	5,558,644 A	9/1996 Boyd et al.	6,409,720 B1	6/2002	Hissong et al.
	5,564,440 A	10/1996 Swartz et al.	6,454,758 B1	9/2002	Thompson et al.
	5,571,088 A	11/1996 Lennox	6,474,340 B1	11/2002	Vaska et al.
	5,571,215 A	11/1996 Serman et al.	6,484,727 B1	11/2002	Vaska et al.
	5,575,772 A	11/1996 Lennox	6,514,249 B1	2/2003	Maguire et al.
	5,582,609 A	12/1996 Swanson et al.	6,514,250 B1	2/2003	Jahns et al.
	5,584,803 A	12/1996 Stevens et al.	6,517,536 B2	2/2003	Hooven et al.
	5,590,657 A	1/1997 Cain et al.	6,527,767 B2	3/2003	Wang et al.
	5,626,607 A	5/1997 Malecki et al.	6,544,262 B2	4/2003	Fleischman
	5,628,316 A	5/1997 Swartz et al.	6,546,934 B1	4/2003	Ingle et al.
	5,630,837 A	5/1997 Crowley	6,575,696 B1	6/2003	Lyons
	5,640,955 A	6/1997 Ockuly et al.			
	5,656,028 A	8/1997 Swartz et al.			
	5,676,692 A	10/1997 Sanghvi			
	5,690,611 A	11/1997 Swartz et al.			
	5,697,949 A	12/1997 Giurtino et al.			
	5,715,818 A	2/1998 Swartz et al.			

(56)

References Cited**U.S. PATENT DOCUMENTS**

6,582,423	B1	6/2003	Thapliyal et al.	
6,605,084	B2	8/2003	Acker et al.	
6,645,202	B1	11/2003	Pless et al.	
6,689,128	B2	2/2004	Sliwa et al.	
6,701,931	B2	3/2004	Sliwa et al.	
6,719,755	B2	4/2004	Sliwa et al.	
6,740,080	B2	5/2004	Jain et al.	
6,745,080	B2	6/2004	Koblish	
6,767,346	B2	7/2004	Damasco	
6,771,996	B2	8/2004	Bowe et al.	
6,802,840	B2	10/2004	Chin et al.	
6,805,128	B1	10/2004	Pless et al.	
6,805,129	B1	10/2004	Pless et al.	
6,837,887	B2	1/2005	Woloszko et al.	
6,840,936	B2	1/2005	Sliwa et al.	
6,858,003	B2	2/2005	Evans et al.	
6,858,026	B2	2/2005	Sliwa et al.	
6,929,010	B2	8/2005	Vaska et al.	
6,942,661	B2	9/2005	Swanson	
6,942,662	B2	9/2005	Goble et al.	
6,949,095	B2	9/2005	Vaska et al.	
6,971,394	B2	12/2005	Sliwa et al.	
7,052,493	B2	5/2006	Vaska et al.	
7,213,601	B2	5/2007	Stevens et al.	
7,338,486	B2	3/2008	Sliwa et al.	
7,387,126	B2	6/2008	Cox et al.	
7,399,300	B2	7/2008	Bertolero	
7,517,345	B2	4/2009	Cox	
7,674,257	B2	3/2010	Pless et al.	
7,699,845	B2	4/2010	Podmore et al.	
7,955,325	B2	6/2011	Wittenberger	
2002/0013579	A1	1/2002	Silvestrini	
2002/0019627	A1	2/2002	Maguire et al.	
2002/0042610	A1	4/2002	Sliwa et al.	
2002/0111567	A1	8/2002	Vanden Hoek et al.	
2002/0128639	A1	9/2002	Pless et al.	
2003/0208209	A1 *	11/2003	Gambale et al.	606/144
2004/0054369	A1	3/2004	Nelson et al.	
2004/0267086	A1	12/2004	Anstadt et al.	
2005/0245918	A1	11/2005	Sliwa et al.	
2005/0251125	A1	11/2005	Pless et al.	
2006/0004352	A1	1/2006	Vaska et al.	

2006/0135954	A1	6/2006	Sliwa et al.	
2006/0184167	A1	8/2006	Vaska et al.	
2006/0200119	A1	9/2006	Vaska et al.	
2007/0249999	A1 *	10/2007	Sklar et al.	604/101.05
2007/0255276	A1	11/2007	Sliwa et al.	
2007/0293854	A1	12/2007	Pless et al.	
2007/0293855	A1	12/2007	Sliwa et al.	
2007/0299496	A1	12/2007	Podmore et al.	
2008/0045936	A1	2/2008	Vaska et al.	
2008/0045946	A1	2/2008	Vaska	
2008/0189932	A1 *	8/2008	Sliwa et al.	29/594
2009/0030270	A1 *	1/2009	Arai et al.	600/37
2009/0192603	A1	7/2009	Ryan	
2010/0016786	A1	1/2010	Drewns et al.	
2010/0081987	A1 *	4/2010	Christian	604/21

FOREIGN PATENT DOCUMENTS

WO	WO-99/02096	1/1999
WO	WO-01/05306	1/2001
WO	WO-01/80708	11/2001
WO	WO-02/102231	12/2002

OTHER PUBLICATIONS

“Supplementary European Search Report”, EP03759515.4-1265 Nov. 8, 2010.

Athanasious, Thanos et al., “Expanded use of suction and stabilization devices in cardiothoracic surgery” *The Society of Thoracic Surgeons*, Apr. 2003.

Cox, James L. et al., “The surgical treatment of atrial fibrillation”, *I. Summary of the current concepts of the mechanism of atrial flutter and atrial fibrillation: J Thorac Cardiovasc Surgery*, vol. 101, Apr. 1991, 402-405.

Cox, James L. et al., “The surgical treatment of atrial fibrillation”, *J Thorac Cardiovasc Surgery*, vol. 101 1991, 406-426.

Cox, James L. “The surgical treatment of atrial fibrillation”, *J Thorac Cardiovasc Surgery*, vol. 101 Apr. 1991, 584-592.

Cox, James L. , “The surgical treatment of atrial fibrillation”, *J Thorac Cardiovasc Surgery*, vol. 101 Apr. 1991, 584-592.

Kiser, Andy C. et al., “The annals of thoracic surgery”, *Evaluation of a Novel Epicardial Atrial Fibrillation Treatment System* 2008.

* cited by examiner

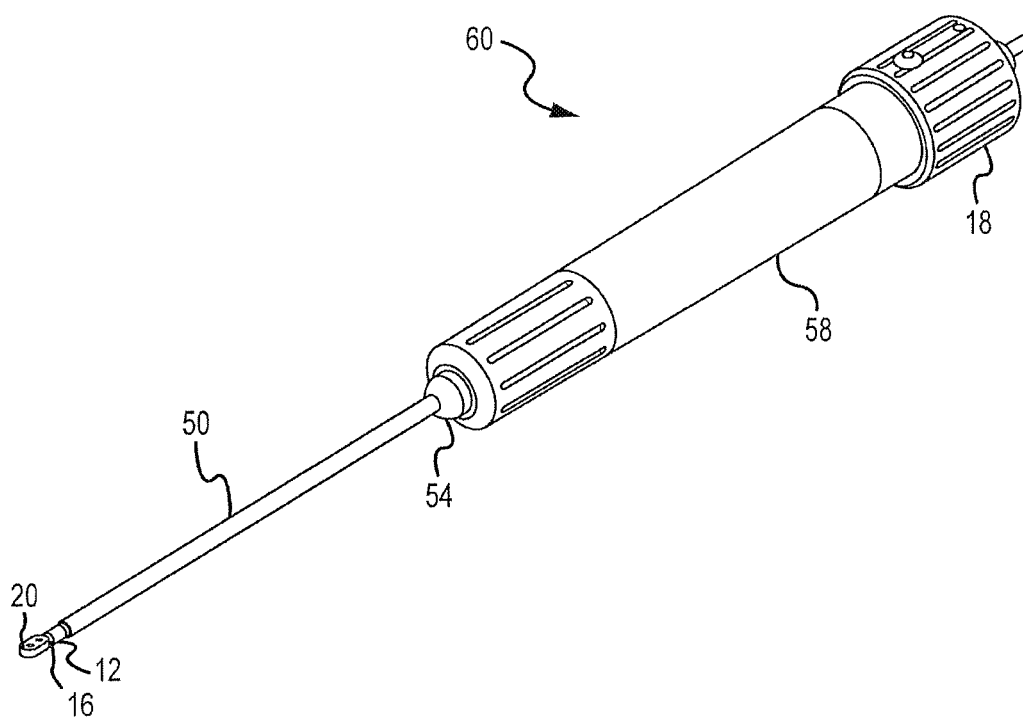


FIG.1

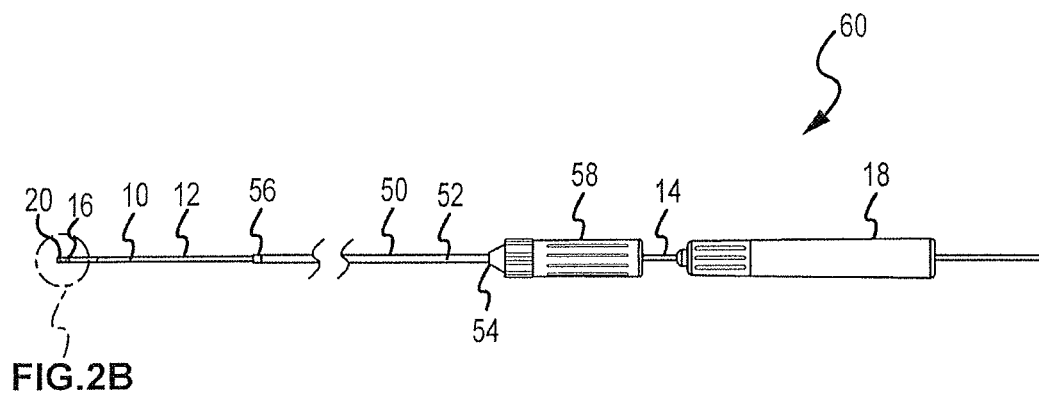


FIG. 2A

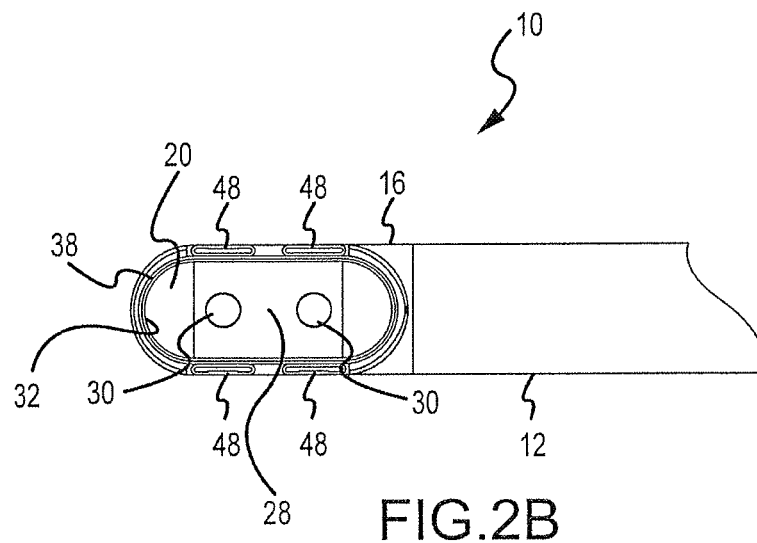
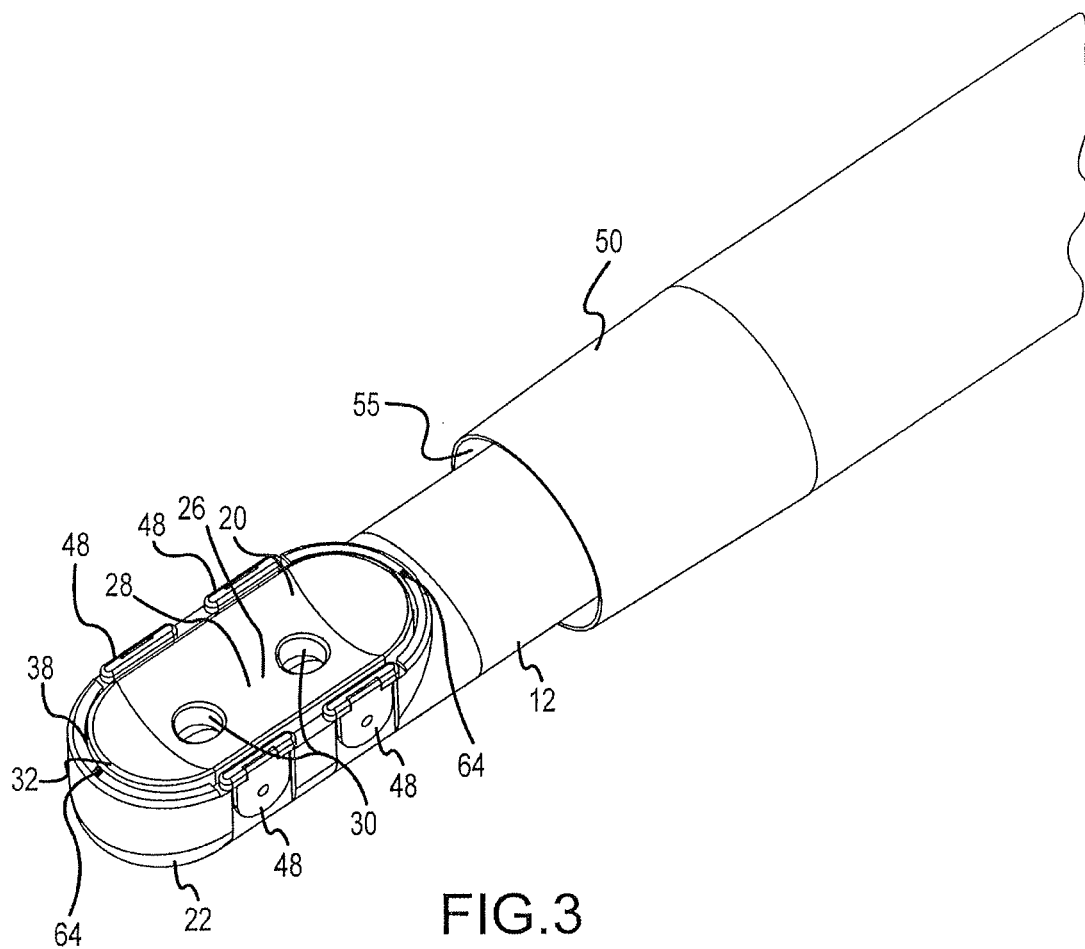
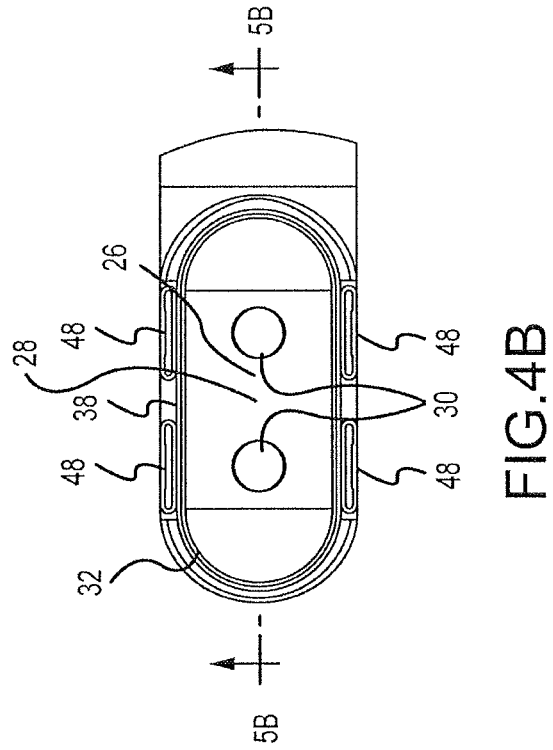
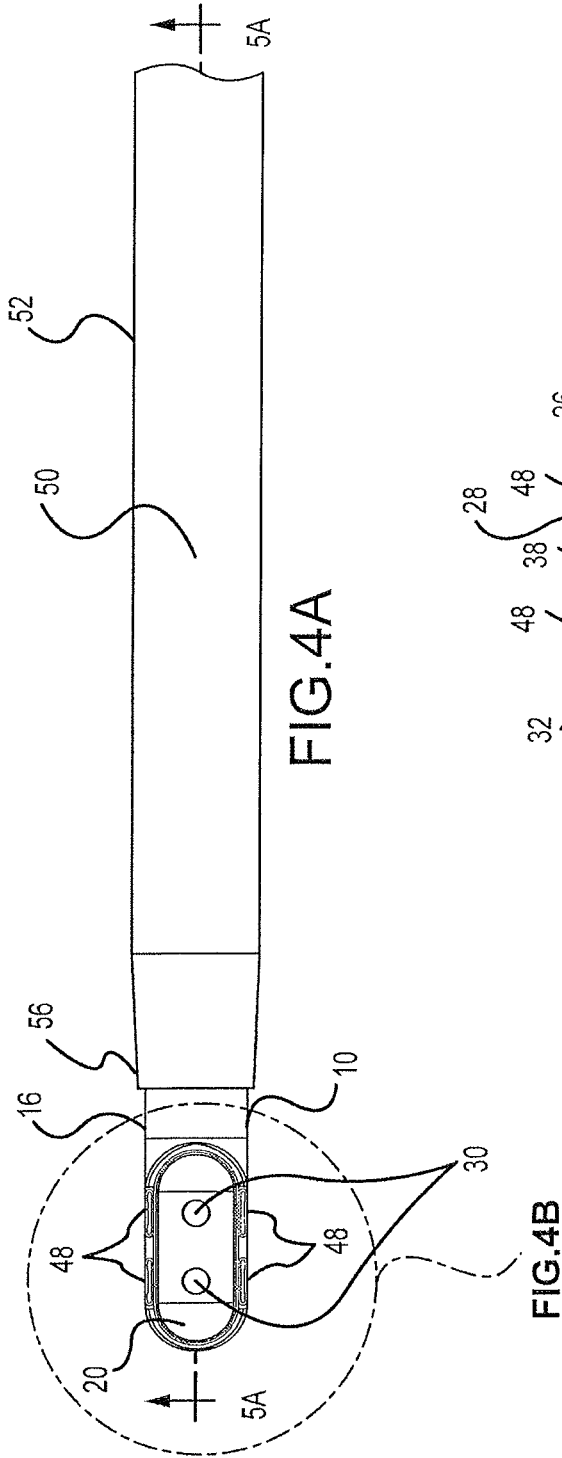


FIG. 2B





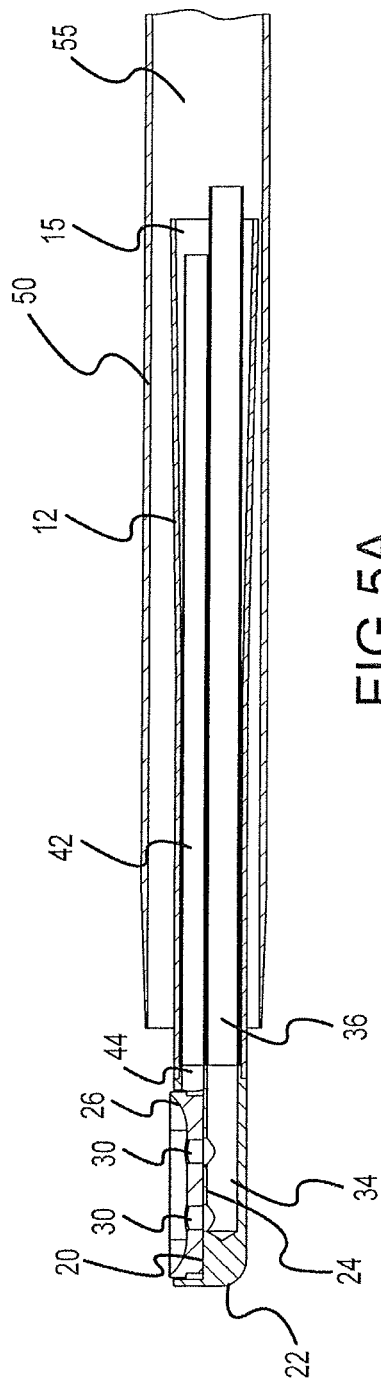


FIG. 5A

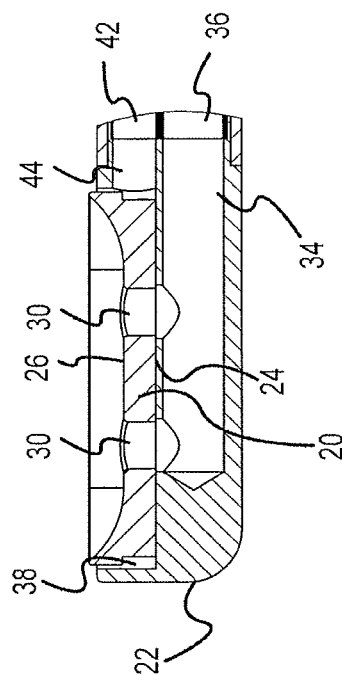


FIG. 5B

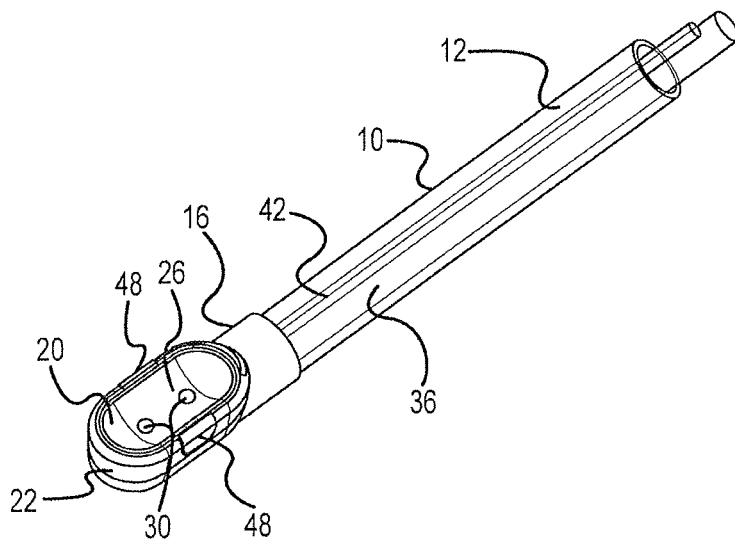


FIG.6

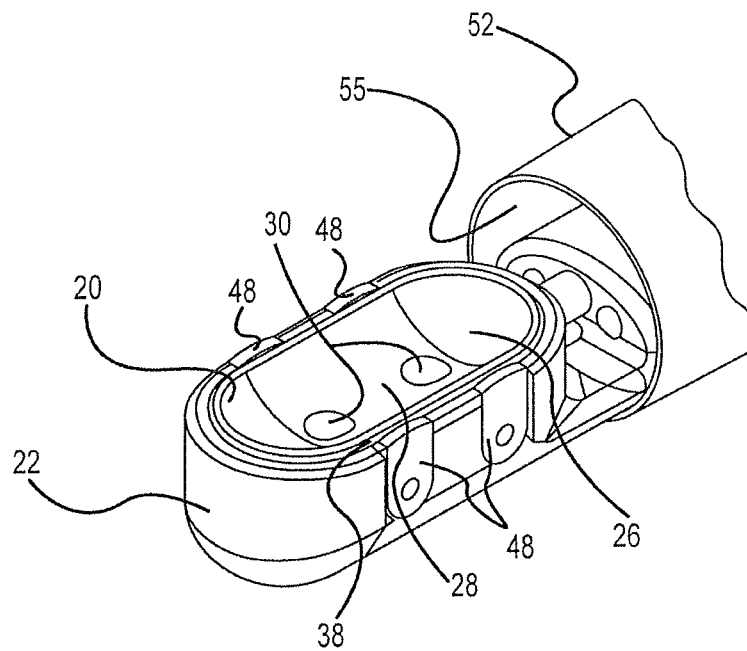
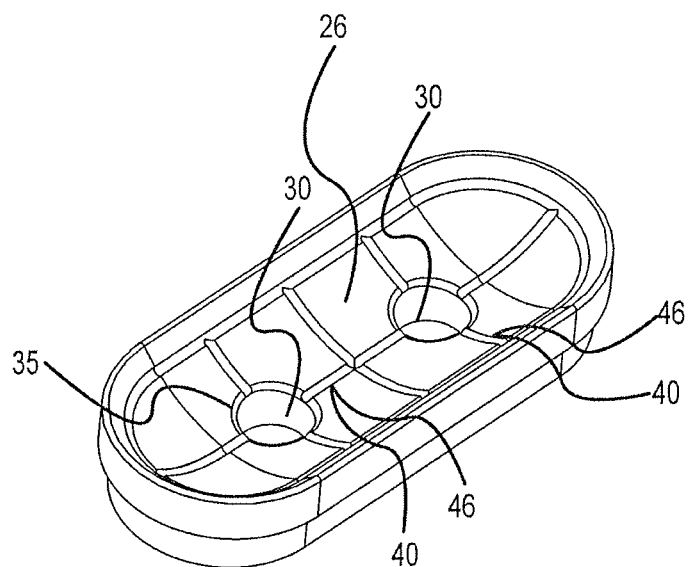
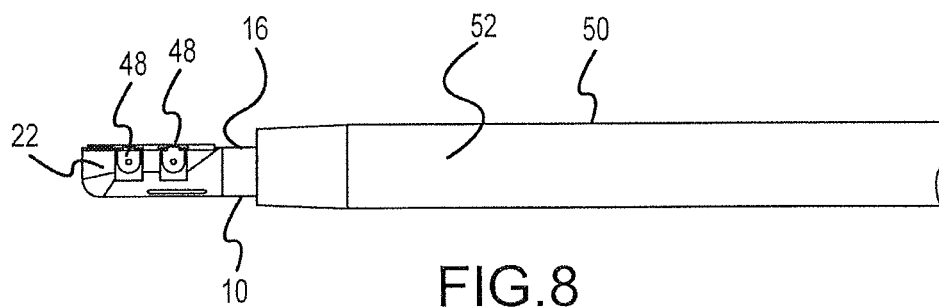


FIG. 7



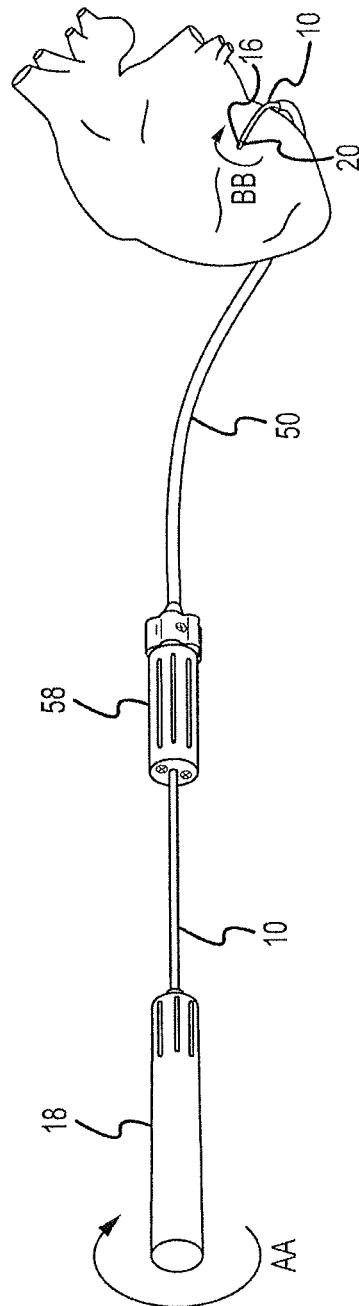
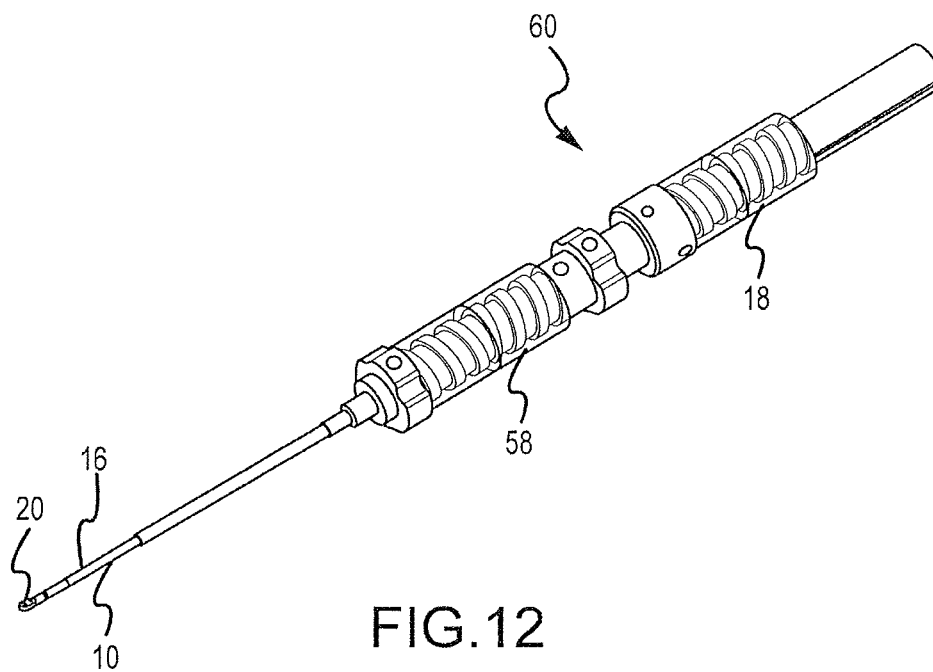
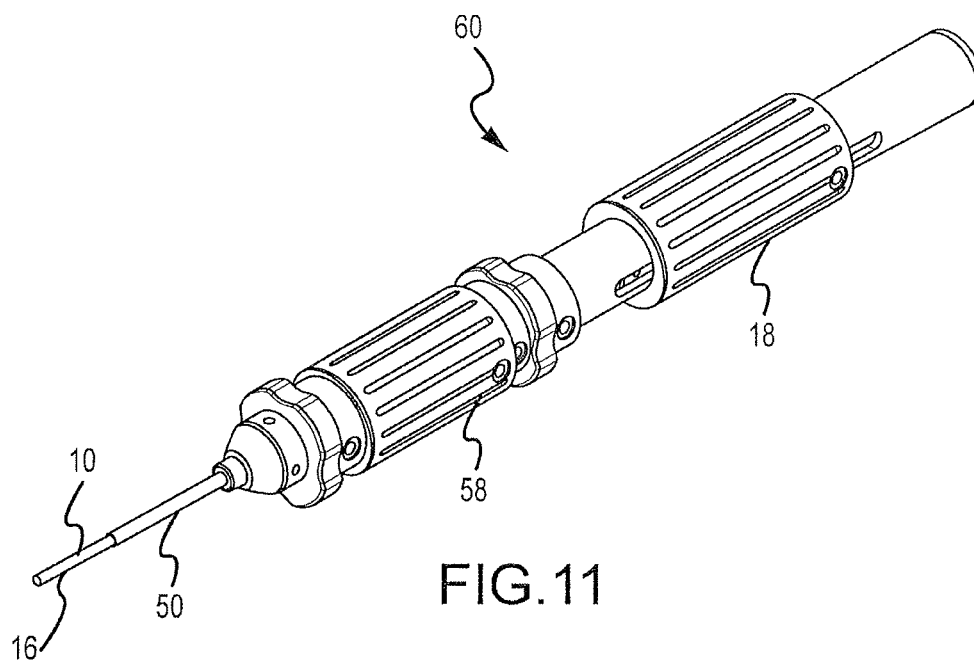


FIG.10



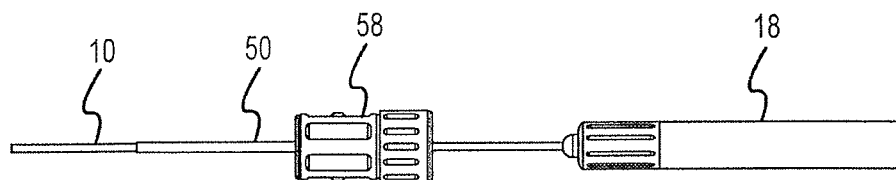


FIG.13

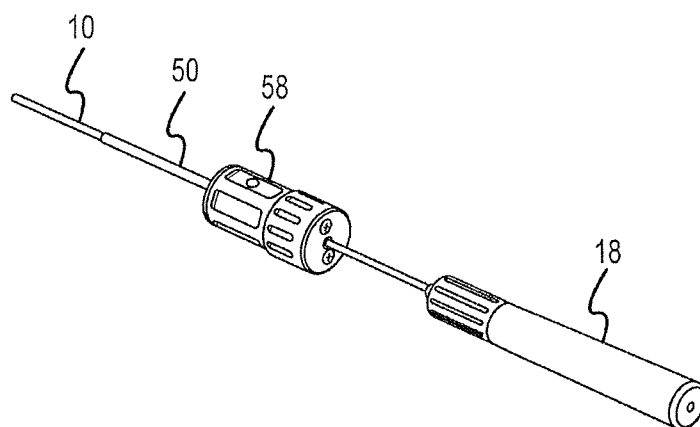


FIG.14

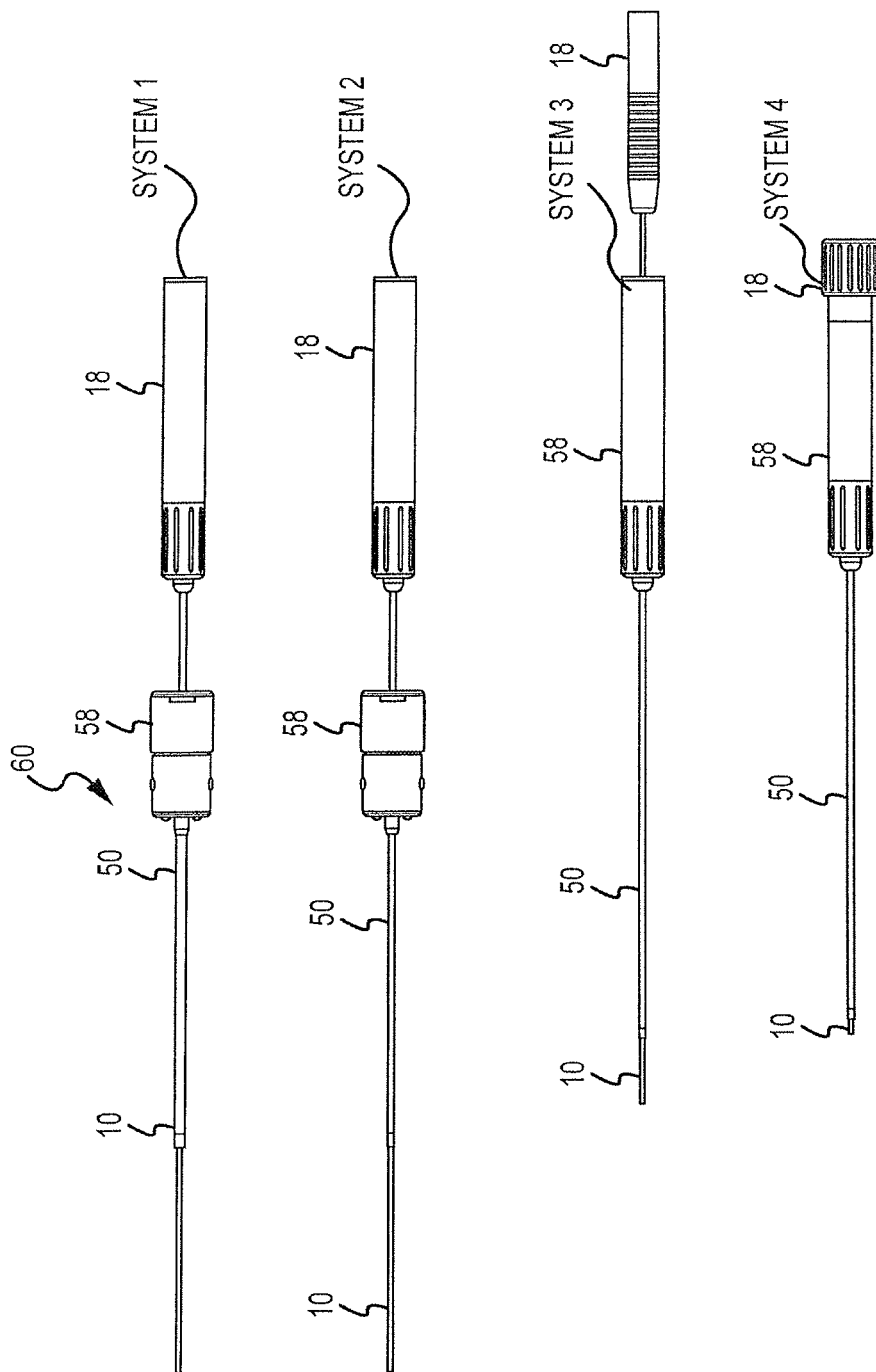


FIG.15

VACUUM-STABILIZED ABLATION SYSTEM**CROSS-REFERENCE TO RELATED APPLICATIONS**

This application is a continuation-in-part of U.S. application Ser. No. 12/408,632 filed 20 Mar. 2009, which claims the benefit of U.S. provisional application No. 61/101,972 filed 1 Oct. 2008. This application is also related to U.S. application Ser. No. 11/785,427, filed 17 Apr. 2007. Each of the foregoing is hereby incorporated by reference as though fully set forth in their respective entireties herein.

BACKGROUND OF THE INVENTION**a. Field of the Invention**

The present disclosure pertains generally to an electrophysiological device and method for providing energy to biological tissue and, more particularly, to a family or group of ablation systems that employ a form of vacuum stabilization to provide greater contact between at least one ablation element and a targeted volume of tissue.

b. Background Art

Ablation of a volume of target tissue can involve moving and non-moving organs such as a kidney or liver and a heart, respectively. In the latter case, the heart beats or contracts when an electrical impulse originating from the sinoatrial node (SA node) travels through the right and left atria, and then activates the atrioventricular node (AV node). From the AV node, the electrical impulse travels through the right and left ventricles via a group of specialized fibers called the His-Purkinje fibers. The impulse causes synchronized contraction of the chambers of the heart. Cardiac conduction irregularities, or any change from the normal sequence of electrical impulses, can cause various arrhythmias, such as atrial fibrillation, atrial flutter and certain ventricular arrhythmias. These conditions can decrease cardiac output and reduce tissue perfusion to the detriment of a subject.

Cardiac ablation is a procedure for treating various arrhythmias by selectively damaging heart tissue in the region where aberrant or abnormal electrical activity is occurring. The damaged tissue blocks the aberrant pathways and restores normal heart rhythm. Various energy delivery schemes may be used, including, but not limited to, cryogenic ablation, radiofrequency (RF) ablation, laser ablation, ultrasound ablation, and microwave ablation. Ablation devices are used to create linear lesions or tiny scars that cut-off or disconnect the abnormal electrical pathway.

Ablation procedures rely on stable contact between the medical device and the targeted tissue. For certain ablation procedures involving the cardiac anatomy, such as a left atrial pulmonary vein isolation (PVI) procedure, the epicardial surfaces of posterior portions of a heart must be accessed. To reach such surfaces from an anterior location (e.g., via a minimally invasive subxiphoid incision) requires the catheter, in particular the distal portion of an elongate catheter, to traverse a tortuous route to reach target tissue. Establishing adequate contact with the target tissue to successfully perform a PVI (i.e., create a continuous lesion or set of connected lesions around one or more pulmonary veins) presents challenges to the practitioner. Furthermore, in some transvenous catheter applications, the point of electrode-tissue contact is as far as about 150 cm away from the point of application of force. These challenges give rise to functional and theoretical challenges associated with conventional devices, and thus, the ability to accurately stabilize the device at the point of contact with a line of target tissue is increasingly important.

The use of reduced pressure, for example by applying a vacuum at or near the point of contact between the medical device and the target tissue, has been contemplated for adhering the device to tissue.

There is a need for electrophysiological devices that provide greater contact stability for control of medical treatments involving contact with a volume of targeted tissue.

There is a need for improved ablation elements that provide greater stability, i.e., limit relative motion between the ablating element and the tissue at the point of contact.

BRIEF SUMMARY OF THE INVENTION

The systems and methods described herein are useful for the ablation of cardiac tissue for treating cardiac conduction irregularities that can cause various arrhythmias such as atrial fibrillation, atrial flutter and certain ventricular arrhythmias. In particular, the systems and methods described herein are useful for the ablation of epicardial tissue via a percutaneous subxiphoid approach. Disclosed herein are vacuum-stabilized ablation devices that include ablating elements capable of providing regions of relatively low pressure to maintain the ablating element in a stable position relative to the tissue, or minimize relative movement of the ablating element relative to the tissue. The devices of the present invention may also include one or more pairs of electrodes positioned on opposite sides of the ablating element, for example, for both orienting the ablating element and confirming contact with a portion of active myocardial substrate, as well as for diagnostic purposes (e.g., confirming conduction block, if desired). Also disclosed herein are methods of using the improved devices in cardiac ablation procedures.

An object of the present invention is to provide ablation systems having improved stability at the point of contact.

Another object of the present invention is to provide ablation systems incorporating ablating elements having integrated vacuum capture mechanisms.

A further object of the present invention is to provide ablation systems having directional ablating elements and means for orienting the ablating elements relative to a target tissue.

Disclosed herein is a tissue ablation apparatus including: a body having at least a first lumen and a second lumen extending therethrough and an ultrasound ablation element positioned within a distal region of the body. The ultrasound ablation element includes: an ultrasound transducer and a membrane extending over at least a portion of the ultrasound transducer, thereby defining a cavity between the membrane and the ultrasound transducer. The second lumen is coupled to the cavity to define a fluid pathway. The apparatus also includes a first orifice in the body proximal of the ultrasound ablation element and open to the first lumen to define a first vacuum pathway; a distal vacuum chamber defined by the body distal of the ultrasound ablation element and in communication with the first lumen to define a second vacuum pathway; a second orifice in the body distal of the ultrasound ablation element and open to the distal vacuum chamber; and at least one flow control apparatus positioned to regulate flow through one of the vacuum pathways independent of flow through the other vacuum pathway.

In certain aspects, the tissue ablation apparatus further includes a third lumen coupled to the first lumen. The third lumen can be in communication with the distal vacuum chamber, and the second vacuum pathway can include the third lumen. Typically, an interior cross-sectional area of the first lumen is about 10 to about 20 times greater than an interior cross-sectional area of the third lumen.

It is contemplated that the at least one flow control apparatus can include: a first flow control apparatus positioned to regulate flow through the first vacuum pathway independent of flow through the second vacuum pathway and a second flow control apparatus positioned to regulate flow through the second vacuum pathway independent of flow through the first vacuum pathway.

Optionally, the fluid pathway can include an outlet that opens into the second vacuum pathway. A fluid flow control apparatus can be positioned to regulate fluid flow through the outlet of the fluid pathway and into the second vacuum pathway. For example, the fluid flow control apparatus can have an inlet and an outlet, and the inlet of the fluid flow control apparatus can have a cross-sectional area between about 4 and about 20 times greater than a cross-sectional area of the outlet of the fluid flow control apparatus.

The at least one flow control apparatus can include an iris. An actuator can be coupled to the body and mechanically and operably linked to the iris in order to vary an effective size thereof. Alternatively, the at least one flow control apparatus can include a passive flow regulating apparatus.

Also disclosed herein is a tissue ablation apparatus including: a body having at least a first lumen and a second lumen extending therethrough and an ultrasound ablation element positioned within a distal region of the body. The ultrasound ablation element includes an ultrasound transducer and a membrane extending over at least a portion of the ultrasound transducer, thereby defining a cavity between the membrane and the ultrasound transducer. The second lumen can be coupled to the cavity to define a fluid pathway. The tissue ablation apparatus also generally includes: a first orifice in the body proximal of the ultrasound ablation element and open to the first lumen to define a first vacuum pathway; a second orifice in the body distal of the ultrasound ablation element and open to the first lumen to define a second vacuum pathway, wherein the fluid pathway is coupled to the second vacuum pathway; a flow control apparatus positioned to regulate flow through the second vacuum pathway independent of flow through the first vacuum pathway; and a fluid flow control apparatus positioned to regulate flow through the fluid pathway into the second vacuum pathway.

The fluid flow control apparatus can, for example, be positioned at a junction between the fluid pathway and the second vacuum pathway. Likewise, the flow control apparatus can, for example, be positioned at a distal end of the first lumen.

At least one of the fluid flow control apparatus and the flow control apparatus can include an iris. An actuator can then be coupled to the elongate body and mechanically and operably linked to the iris to adjust an effective size thereof. Alternatively, at least one of the fluid flow control apparatus and the flow control apparatus can include a passive flow regulating apparatus.

In another aspect of the disclosure, a tissue ablation apparatus includes: a tubular body having a proximal end and a distal region; a vacuum lumen extending through the tubular body from the proximal end to the distal region; an irrigation lumen extending through the tubular body from the proximal end to the distal region; and an ultrasound ablation element positioned within the distal region of the tubular body. The ultrasound ablation element includes: an ultrasound transducer and a membrane extending over at least a portion of the ultrasound transducer, thereby defining a cavity between the membrane and the ultrasound transducer, wherein the irrigation lumen discharges into the cavity. The tissue ablation apparatus also generally includes a first vacuum orifice through the tubular body into the vacuum lumen proximal of the ultrasound ablation element; a second vacuum orifice

through the tubular body into the vacuum lumen distal of the ultrasound ablation element, a fluid discharge orifice in communication with the cavity and proximate a junction between the second vacuum orifice and the vacuum lumen; and at least one means for controlling a flow through one of the first vacuum orifice, the second vacuum orifice, and the fluid discharge orifice independent of others of the first vacuum orifice, the second vacuum orifice, and the fluid discharge orifice.

According to certain aspects, the at least one means for controlling a flow includes: a first means for controlling a flow through one of the first and second vacuum orifices independent of the other of the first and second vacuum orifices and the fluid discharge orifice; and a second means for controlling a flow through the fluid discharge orifice independent of flow through the first and second vacuum orifices. The at least one means for controlling a flow may be active or passive.

The foregoing and other aspects, features, details, utilities, and advantages of the present invention will be apparent from reading the following description and claims, and from reviewing the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of one embodiment of an ablation system according to the present invention.

FIG. 2A is a top view of another embodiment of an ablation system according to the present invention having a guiding catheter and a coaxial ablation catheter.

FIG. 2B depicts a top view of the distal portion of the ablation catheter depicted in FIG. 2A.

FIG. 3 illustrates a close-up perspective view of the distal portion of an ablation catheter in a coaxial relationship with a guiding catheter.

FIG. 4A is a top view of a distal portion of an ablation system described herein.

FIG. 4B is an enlarged view of the ablation tip depicted in FIG. 4A.

FIG. 5A depicts a cross-sectional elevation view of the ablation system depicted in FIG. 4A taken along line A-A.

FIG. 5B is an enlarged cross-sectional elevation view of the ablation tip depicted in FIG. 5A.

FIG. 6 illustrates a partial perspective view of an ablation catheter described herein.

FIG. 7 depicts a partial perspective view of the distal portion of an ablation system described herein.

FIG. 8 is a side elevation view of an ablation system described herein.

FIG. 9 is an enlarged perspective view of an ablating element having a textured surface.

FIG. 10 is a simplified, perspective view depicting an ablation system contacting an epicardial surface as described herein.

FIG. 11 illustrates a perspective view of a handle design for use with the present ablation systems.

FIG. 12 is a fragmentary view illustrating exemplary internal portions of the handle depicted in FIG. 11.

FIG. 13 is a side view depicting another handle design for ablation systems described herein.

FIG. 14 is a perspective view of the handle design depicted in FIG. 13.

FIG. 15 illustrates various ablation system configurations as described herein.

FIG. 16 is a perspective, cut-away view of a tissue ablation apparatus according to another aspect of the disclosure.

FIGS. 17A through 17C depict various flow regulation apparatuses.

DETAILED DESCRIPTION OF THE INVENTION

Described herein are tissue ablation systems useful, for example, in the treatment of cardiac conduction irregularities that can cause acute and chronic arrhythmias, such as atrial fibrillation, atrial flutter, and ventricular rhythm disorders. The systems and methods will be described in connection with epicardial tissue ablation utilizing electrically-activated electrodes (e.g., acoustic or high intensity focused ultrasound (HIFU), radiofrequency (RF) electrodes, and the like); however, it is contemplated that the described features may be incorporated into or combined with other energy delivery schemes (e.g., cryogenic, chemical, etc.), as would be appreciated by one of ordinary skill in the art by virtue of the teachings herein.

With reference to FIG. 1, an ablation system 60 is shown. The ablation system 60 includes an ablation catheter 10 and a coaxial guiding catheter 50. An ablating element 20 is disposed on the distal portion 16 of the ablation catheter 10. The guiding catheter 50 includes a handle 58 attached to the proximal end portion 54.

Referring to FIGS. 1, 2A/B, 3, 4A/B, 5A/B, and 6-8, the guiding catheter 50 includes an elongate body 52 having a lumen 55 extending therethrough, a proximal end portion 54, a distal end 56 and a handle 58 connected to the proximal end portion 54. In one embodiment, a distal portion 62 of the guiding catheter 50 comprises a preformed member having a curved configuration, such as an arbitrary or complex shape, or the like, or as illustrated in FIG. 10, a partial hoop, hook or C-shape. In another embodiment, the guiding catheter 50 includes steering mechanisms or elements, such as resilient pull wires and anchor rings, making it steerable by an operator. That is, structure that permits the distal portion 62 to curve and/or deflect to access a desired target tissue location or ablation site.

The ablation catheter 10 slides axially within the lumen 55 of the guiding catheter 50 in coaxial relationship. The ablation catheter 10 includes an elongate body 12 having a lumen 15 extending therethrough, a proximal end 14 and a distal portion 16. A handle 18 mechanically couples to the proximal end 14 of the elongate body 12. The distal portion 16 includes one or more ablating elements 20. A single ablating element 20 (as depicted in the figures) or two or more ablating elements 20 can operatively couple to the distal portion 16 of the elongate body 12.

Referring to FIGS. 3 and 5B, for example, the ablating element 20 is mounted in a housing 22 that is affixed to the distal end of the elongate body 12. The ablating element 20 includes a first surface 24 disposed within the interior of the housing 22 and a second surface 26 opposite the first surface 24. The second surface 26 provides an interface between the ablating element 20 and the tissue. During use, the second surface 26 is oriented towards and positioned adjacent to a target tissue for ablation. The second surface 26 has a base portion 28 and a rim 32 that defines the perimeter or circumference of the ablating element 20. At least one port 30 extends through the ablating element 20 from the first surface 24 to the second surface 26. In one embodiment, the at least one port 30 extends through the base portion 28 of the second surface 26, but it is contemplated that the at least one port 30 may extend through any portion of the second surface 26 between the base portion 28 and the rim 32. The at least one port 30 is coupled to a source of varying pressure (not shown), for example a vacuum pump. Activation of the source of

varying pressure results in a pressure differential between the ablating element 20 and the tissue, the second surface 26 defining a region of lower pressure compared to the ambient pressure, that draws the ablating element towards the tissue and stabilizes the device relative to the tissue.

In one embodiment, the second surface 26 has a curved or concave shape, such as the hemicapsule shape depicted in the figures. A hemicapsule shape is described as a cylinder capped with hemispheres that is divided in half along the axis of the cylinder. Other variations of the hemicapsule shape are also possible, for example, a hemisphere, a hemicylinder, and a hemi-ellipsoid, or any other configuration that provides for a volume of space that increases the effective surface area of the second surface 26. The concave shape allows the second surface 26 to conform to the contours of the target tissue. The concave shape also permits the ablating element 20 to be drawn towards the tissue when a vacuum is applied so that the ablating element 20 can be maintained in a stable position relative to the tissue. While various curved or concave shapes have been discussed herein, it is also contemplated that the second surface 26 may be flat.

In another embodiment, the ablating element 20 is a radiofrequency (RF) ablating element. The RF ablating element is a conductive metal having, in one embodiment, a concave surface as described above. The metal may be any conductive metal or a metal alloy consisting of one or more of gold, silver, platinum, iridium, titanium, tantalum, zirconium, vanadium, niobium, hafnium, aluminum, silicone, tin, chromium, molybdenum, tungsten, manganese, beryllium, cobalt, nickel, palladium, osmium, rhenium, technetium, rhodium, ruthenium, cadmium, zinc, germanium, antimony, bismuth, boron, scandium and metals of the lanthanide and actinide series, or any other biocompatible material. In some embodiments, it may be desirable to include a layer of biocompatible material covering the conductive metal. In another embodiment, the ablation catheter 10 may incorporate other types of ablating elements suitable for forming ablation lesions such as a microwave transmitter, a cryogenic element, an optical element, or an acoustic transducer, for example a high intensity focused ultrasound transducer.

In one embodiment, the ablating element 20 has a length of about 5 mm to about 10 mm and has a width of about 1 mm to about 5 mm. In another embodiment, the ablating element has a length of about 6 mm and a width of about 3.25 mm. In a further embodiment, the ablating element has a length of about 7 mm and a width of about 3.25 mm. It is to be understood that the ablating element 20 does not necessarily have a rectangular shape as the described dimensions may suggest, but may have the concave or hemispherical shapes discussed herein. Thus, the dimensions provided are merely exemplary and are not intended to be limiting.

As previously noted, the ablating element 20 includes at least one port 30 extending through the ablating element 20 from the first surface 24 to the second surface 26. The at least one port 30 is an opening or aperture that extends through the ablating element 20. The at least one port 30 is coupled to a source of varying pressure (not shown) so that a low pressure region can be established between the second surface 26 of the ablating element 20 and the target tissue. Two ports 30 are depicted in the embodiment shown in FIG. 3. In other embodiments, the ablating element 20 includes a single port 30 or more than two ports as would be appreciated by a person of skill in the art. The size of the ports 30 is selected to provide a region of relatively low pressure as between the ablating element 20 and the tissue, such as through the application of a vacuum, to maintain the ablating element 20 in a stable position relative to the tissue, and at the same time to reduce

the risk that the tissue may be drawn into the ports **30**, thus occluding or impeding the ports **30**. The size and number of the ports **30** may be varied according to the application.

In one embodiment, the port **30** is circular, however, as a person of skill in the art appreciates, the shape of the one or more ports **30** can be designed and fabricated having diverse and/or differing shapes and cross-sectional areas, for example, having an oval, square, rectangular, slit, or any other regular or irregular shape, area, and cross-section. In another embodiment, the port **30** may be substantially circular with a plurality of narrow off-shoots or appendages extending radially outwardly to form a star-like configuration.

Referring to FIGS. **5A** and **5B**, the ports **30** couple to at least one suction lumen **36**. The suction lumen **36** extends through the elongate body **12** and may be connected to a source of varying pressure (not shown), such as a vacuum source. The suction lumen **36** may be a tube or other channel. The suction lumen **36** may connect directly to the ports **30**, or the suction lumen **36** may couple to a suction cavity **34** that connects to the ports **30**. The suction cavity **34** can serve as a manifold to couple multiple ports **30** to the suction lumen **36**. If the ablation catheter **10** includes more than one port **30**, a separate suction lumen **36** may be coupled to each port **30**, or a single suction lumen **36** may be coupled to each of the ports **30**. The suction lumen **36** may be a separately-formed tube or lumen extending through the lumen **15** of the elongate body **12**, or the suction lumen **36** may be integrally-formed within the lumen **15** of the elongate body **12**. In use, when the vacuum source is activated, an area of low pressure relative to the ambient pressure is formed in the region of the ports **30** on the second surface **26**, which draws the ablating element **20** towards the adjacent target tissue.

In another embodiment, the suction lumen **36** can be operated in a reverse flow manner. In this embodiment, the suction lumen **36** is coupled to a source of fluid, for example saline, and fluid is delivered through the suction lumen **36** and the ports **30** to expel or remove obstructions or debris. The suction lumen **36** may be interchangeably coupled to both a source of fluid and a source of varying pressure via a valve, or the suction lumen **36** may be manually coupled to either a source of fluid or a source of varying pressure to switch between a stabilizing mode and an irrigating mode.

Referring now to FIG. **9**, in one embodiment, the ablating element **20** includes an anti-occlusion element **40** on the second surface **26** that prevents the tissue from being drawn into the ports **30** and occluding the ports **30** resulting in loss of tissue capture. In embodiments having two or more ports, occluding one port may result in loss of contact at the other ports. Thus, it is useful to provide a mechanism to reduce or eliminate the incidence of port occlusion. As shown in FIG. **9**, the anti-occlusion element **40** may be a series of grooves **46** formed on the second surface **26** of the ablating element **20**. The grooves **46** are depressions, textures or indentations formed or etched on the second surface **26** that communicate with the port **30**. In other words, the grooves **46** connect to or join an outer edge **35** of the at least one port **30**. In one embodiment, the anti-occlusion element **40** may include a series of grooves **46** expanding radially outwardly from the outer edge **35** of the port **30** to the rim **32**. In another embodiment, the anti-occlusion element **40** may include a series of ridges or protuberances (not illustrated) on the second surface **26**. The ridges or protuberances may be raised elements arranged in various patterns to give the second surface **26** texture or roughness.

In yet a further embodiment, the anti-occlusion element **40** may include a conductive mesh or screen (not shown) overlying and adhered to at least a portion of the second surface

26. The conductive mesh or screen prevents tissue from being sucked into the port **30** and clogging or plugging the port **30**. In one embodiment, the mesh or screen is thermally conductive and/or non-attenuating so that it does not interfere with the delivery of ablative energy during use—the ablative energy will transmit through the mesh or screen. In another embodiment, the conductive mesh or screen is made of a metallic material, such as a metallic wire, alloy or clad material, a conductive polymer material, a conductive composite material, or a conductive fibrous material. The conductive mesh or screen overlays and is affixed to the second surface **26** and may be electrically coupled to the ablating element **20**. Alternatively, the mesh or screen may be made of an RF-transmissive (i.e., non-attenuating), non-conductive material such as a polymer. The mesh or screen may overlay the entire surface of the second surface **26** or a portion of the second surface **26** that includes the at least one port **30**. A combination of anti-occlusion elements may also be used, for example, both ridges and a mesh or a screen.

In yet another embodiment, a button electrode is disposed on the second surface **26**. The button electrode can be disposed on the base portion **28** of the second surface **26**, or on any portion of the second surface **26** between the base portion **28** and the rim **32**. The second surface **26** may or may not comprise a conductive material. In one embodiment, the second surface **26** is made of a conductive material, and the button electrode is surrounded by or embedded in an insulative material. In another embodiment, the rim **32** is made of a non-metallic, non-conductive and pliant material.

Referring again to FIGS. **3**, **5A** and **5B**, in yet another embodiment, the ablation catheter **10** includes an irrigation channel **38** surrounding at least a portion of the rim **32** of the ablating element **20**. In one embodiment, the irrigation channel **38** completely surrounds the rim **32**. The irrigation channel **38** is a narrow passage or opening that permits a fluid to flow to the tissue in the vicinity of the ablating element **20**. The fluid may be saline, hypertonic saline, water, refrigerant, or the like and may be used to cool the tissue and/or as a transmission medium for delivering energy, such as RF or ultrasonic energy, to the tissue. The irrigation channel **38** is in fluid communication with an irrigation lumen **42**. The irrigation lumen **42** extends through the lumen **15** of the elongate body **12** and couples to a fluid source (not shown). In one embodiment, a distal end of the irrigation lumen **42** couples directly to the irrigation channel **38**. In another embodiment, the irrigation lumen **42** couples to an irrigation inlet port **44** which couples to the irrigation channel **38**. The source of varying pressure and the fluid source can be activated either independently or simultaneously without one interfering with or disrupting the other. Accordingly, control of the source of pressure overcomes any incoming irrigation fluid while maintaining suction stabilization relative to the target tissue.

The ablation catheters described and depicted herein are directional. In other words, successful ablation depends on proper orientation of the ablating element **20** relative to the target tissue. For example, when ablating epicardial tissue, the second surface **26** must be operatively oriented with respect to the target tissue (e.g., towards the cardiac myocytes forming the epicardium).

In a further embodiment, to assist in orienting and locating, the ablation catheter **10** includes one or more electrodes **48** disposed on the distal portion **16** of the elongate body **12** (see FIG. **3**, for example). The electrodes **48** may advantageously be used to orient the ablation catheter **10** to ensure that the second surface **26** of the ablating element **20** is facing or oriented towards the tissue desired to be ablated. In a particular configuration, the electrodes **48** may be unipolar or bipolar

electrogram (EGM) electrodes adapted to measure electrical activity present on a surface of the tissue. For example, in one embodiment, a pair of bipolar electrodes **48** is disposed on an outer surface of the housing **22**, the electrodes in the pair being disposed on opposite sides of the ablating element **20**, as shown in FIG. **6**, for example. In another embodiment, two pairs of bipolar electrodes **48** are used, as shown in FIG. **3**, for example. The electrodes **48** are disposed on opposite sides of the ablating element **20** in a lateral direction generally perpendicular to a central axis of the elongate body **12** of the ablation catheter **10**. Alternatively, or in addition to the foregoing, a bipolar pair of electrodes **48** may be disposed on opposite sides of the ablating element **20** in a lateral direction generally parallel to a central axis of the catheter body. In one embodiment, a side portion of the electrodes **48** (i.e., a portion that is exposed on the side of the housing **22**, as shown in FIG. **3**), is covered in a biocompatible material to prevent pacing and/or sensing of tissue that may contact the side portion of the electrodes **48**. To ensure that the second surface **26** of the ablating element **20** is properly oriented towards the target tissue, the top portion of the electrodes **48** (i.e., the portion that is co-planar with the rim **32** of the second surface **26**), emits and/or senses the pacing and/or sensing signals.

The electrodes **48** are coupled to an EGM-measurement circuit and a display or user interface for displaying EGM data. When the electrodes **48** are touching cardiac tissue, such as the epicardium, the electrodes **48** will sense an EGM signal. This will indicate to the user that the ablating element **20** is properly oriented. If the electrodes **48** do not sense an EGM signal, then the ablating element **20** is not facing cardiac tissue and must be re-oriented until an EGM signal is sensed. A signal can be activated for either or both states (i.e., electrodes coupled and not coupled to cardiac tissue) to alert the operator of a current state via a variety of modalities such as acoustic, visual, haptic or vibratory and the like.

In another embodiment, the electrodes **48** are used for diagnostic purposes, for example, to confirm that an effective lesion has been created. In this embodiment, the electrodes **48** are coupled to an impedance-measuring circuit. An ablation lesion is non-conductive scar tissue; thus, the lesion blocks electrical signals. Because impedance measures resistance, the effectiveness of an ablation lesion can be determined based on impedance measurements. Impedance can be measured before, during or after applying ablative energy to the tissue. If an effective lesion has been created, the impedance will be higher after ablation compared to pre-ablation impedance measurements. Also, impedance can be used to identify a discontinuity in an ablation lesion (i.e., the impedance will be lower near the discontinuity).

In a further embodiment, a pair of electrodes **48** is used to confirm the completeness of a lesion in a pacing and sensing mode. In this embodiment, a pair of electrodes **48** is positioned on opposite sides of the ablating element **20**. A first electrode of the pair of electrodes **48** sends a pacing signal. The second electrode senses or detects the pacing signal only if the lesion is incomplete. Once an effective lesion is made, the second electrode will no longer detect the pacing signal. In this embodiment, the electrodes **48** are connected to a pulse-generator and monitor as is known in the art. In an alternative embodiment, both of the electrodes **48** may be sensing electrodes with both electrodes sensing normal activity. When only one of the electrodes senses the activity an effective lesion has been created.

It is further contemplated that the rim **32** of the ablating element **20** operates as a pacing and/or sensing electrode. During use, the rim **32** of the ablating element **20** contacts the target tissue. Thus, the ablating element **20** can alternate or

cycle between an ablating mode and a pacing and/or sensing mode. In this embodiment, the ablating element **20** is coupled to both an RF generator and a pulse-generator. It may be further desirable to include a suitable filtering and/or shielding mechanism when coupling the ablating element **20** to both a high power, high frequency RF generator and low power, low frequency pacing and sensing circuitry. Because of the relative difference in size between the ablating element **20** and the electrodes **48**, suitable adjustments may need to be made to the pacing parameters. The ablating element **20** can be either unipolar or bipolar. In a bipolar configuration, the ablating element **20** operates with one or more of the electrodes **48** disposed on the housing **22**. In an alternative embodiment, a ring electrode (not shown) is disposed on a distal end of the housing **22**. When the ablating element **20** serves as a single conductor for both the high power, high frequency RF generator

In another embodiment, the ablation device **10** includes one or more temperature sensors **64**, such as thermistors or thermocouples, disposed on the distal portion **16** of the elongate body **12** (see FIG. **3**). The one or more temperature sensors are positioned to measure the temperature of the ablating element **20**, the fluid that flows through the irrigation channel **38** to the tissue, and/or the tissue. In one embodiment, temperature sensors **64** are positioned distally and/or proximally of the ablating element **20** as shown in FIG. **3**. Temperature readings from the one or more temperature sensors **64** may be output and presented as advisory data to a practitioner (analogous to the above relating to the state of the electrode(s)). For example, temperature readings may be presented via a display (e.g., a color, number, or symbol), a tone (e.g., an audible alarm), and/or haptic or vibratory feedback. This allows the practitioner to adjust the rate at which energy is delivered by the ablating element **20** and/or the rate at which a fluid is delivered through the irrigation lumen **42** in order to maintain a particular temperature or temperature range at the tissue.

Referring to FIGS. **2A**, **3** and **10**, the elongate body **12** of the ablation catheter **10** is slidably disposed through the lumen **55** of the guiding catheter **50** in a coaxial configuration. In one embodiment, both the ablation catheter **10** and the guiding catheter **50** are steerable and/or deflectable. In this embodiment, the ablation catheter **10** and the guiding catheter **50** include one or more steering wires or pull wires (not shown) within the elongate bodies **12**, **52** of the ablation catheter **10** and the guiding catheter **50**, respectively. The handle **18** of the ablation catheter **10** and the handle **58** of the guiding catheter **50** include actuators for steering and/or deflecting the catheters. In another embodiment, the handles **18**, **58** are different in size and/or shape so that a practitioner can easily distinguish one from the other during a medical procedure. In a further embodiment, the handles or user interfaces **18**, **58** are tactilely unique, meaning they each have a different feel or texture relative to the other. For example, one handle may have a soft or spongy surface while the other handle has a hard or stiff surface. Alternatively, one handle may have a smooth surface compared to a rough or textured surface on the other handle. It is advantageous to provide an ablation system in which the handles **18**, **58** on the ablation catheter **10** and the guiding catheter **50** are different in size, shape and/or tactility to permit a practitioner to easily and quickly identify and distinguish the handle for controlling the ablation catheter **10** versus the handle for controlling the guiding catheter **50** during a medical procedure. As shown in FIGS. **13** and **14**, in one embodiment, the handle **18** attached to the ablation catheter **10** is longer and more narrow than the handle **58** attached to the guiding catheter **50**.

11

Referring to FIG. 10, the ablation catheter 10 is configured in a coaxial relationship with both the handle 58 of the guiding catheter 50 and the lumen 55 of the guiding catheter 50. The handle 58 on the guiding catheter 50 may be manipulated to steer and/or deflect the guiding catheter 50 to direct the distal end 56 of the guiding catheter 50 to a location near a tissue to be ablated. The handle 18 on the ablation catheter 10 may also be manipulated to steer and/or deflect the ablation catheter 10. The guiding catheter 50 provides a pathway for delivering the distal portion 16 of the ablation catheter 10 to the tissue site for ablation. The guiding catheter 50 also advantageously constrains the ablation catheter 10 within the lumen 55 of the guiding catheter so that the ablating element 20 can be properly oriented against the tissue to be ablated. More specifically, the distal portion 16 of the ablation catheter 10 is advanced distally until the distal portion 16 extends beyond the distal end 56 of the guiding catheter 50. In one embodiment, the distal portion 16 of the ablation catheter 10 is advanced about 5 cm to about 15 cm beyond the distal end 56 of the guiding catheter 50. The handle 18 of the ablation catheter 10 can then be rotated axially as shown by the arrow AA depicted in FIG. 10. Rotating the handle 18 causes the distal portion 16 of the ablation catheter 10 to also rotate axially as shown by the arrow BB. Because it is constrained within the guiding catheter 50, the distal portion 16 of the ablating catheter 10 spins or rotates within the guiding catheter 50, whereas were the distal portion 16 not constrained within the guiding catheter 50, the distal portion 16 would bend and deflect in a random and uncontrollable fashion. Thus, not only does the guiding catheter 50 provide means for guiding the ablation catheter 10 to the desired ablation site, the guiding catheter 50 also advantageously assists in properly orienting the second surface 26 of the ablating element 20 in relation to the tissue to be ablated.

FIGS. 11 and 12 depict the dual-handle configuration in a single system. The ablation system 60 includes a first handle 58 for controlling the guiding catheter 50 and a second handle 18 for controlling the ablation catheter 10. The ablation catheter handle 18 is adapted to move back and forth in a distal and proximal direction to advance and withdrawal the distal portion 16 of the ablation catheter 10 through the guiding catheter 50. The handles 58, 18 are also rotatable axially relative to a longitudinal axis of the catheter bodies.

Referring to FIG. 15, various combinations of handle configurations can be used to provide different levels of control. In addition, the ablation catheter 10 can be made so that it is not removable or separable from the guiding catheter 50. In System 1, the handle 58 for the guiding catheter 50 includes an actuator for deflecting the guiding catheter 50. The handle 18 of the ablation catheter 10 is axially rotatable relative to a longitudinal axis of the elongate catheter body 12 to effect axial rotation of the distal portion 16 of the ablation catheter 10. The ablation catheter handle 18 can be advanced distally to extend the distal portion 16 of the ablation catheter 10 up to about 35 cm beyond the distal end 56 of the guiding catheter 50. The guiding catheter has an inner diameter of about 4-5 mm. The ablation catheter 10 can be removed from the lumen 55 of the guiding catheter 50. System 2 is similar to System 1, however the guiding catheter 50 has an inner diameter of about 3-4 mm, and the ablation catheter 10 is not removable from the lumen 55 of the guiding catheter 50.

In System 3, the handle 18 for the ablation catheter 10 can be advanced distally to extend the distal portion 16 of the ablation catheter 10 up to about 5 cm. The ablation catheter handle 18 is also axially rotatable relative to a longitudinal axis of the elongate catheter body 12 to effect axial rotation of the distal portion 16 of the ablation catheter 10. In System 4, the

12

ablation catheter handle 18 is axially rotatable, but cannot be advanced distally to extend the distal portion 16 of the ablation catheter 10 beyond the distal end 56 of the guiding catheter 50. In both Systems 3 and 4, the guiding catheter has an inner diameter of about 3-5 mm, and the ablation catheter 10 can be removed from the lumen 55 of the guiding catheter 50. The ablation systems described herein may incorporate the handle designs and steering mechanisms used in known steerable introducer systems such as the Agilis™ N×T Steerable Introducer and/or steerable catheter systems such as the Livewire TCT™ Ablation Catheter, currently distributed by St. Jude Medical, Atrial Fibrillation Division, Inc. of St. Paul, Minn.

Methods of ablating tissue will now be described. In one embodiment, the method includes providing a guiding catheter 50 and providing an ablation catheter 10 slidably disposed within a lumen 55 of the guiding catheter 50. The guiding catheter 50 includes an elongate guiding catheter body 52 defining a lumen 55 extending therethrough, a distal end 56, a proximal end portion 54 and a handle 58 mechanically coupled to the proximal end portion 54. The ablation catheter 10 includes some or all of the elements previously described herein. For example, the ablation catheter 10 includes an elongate ablation catheter body 12 having a proximal end 14, a handle 18 mechanically coupled to the proximal end 14, and a distal portion 16 having means for ablating a target tissue. The ablation catheter 10 further includes components to orient the distal portion 16 of the ablation catheter with respect to a target tissue, components to maintain the distal portion 16 of the ablation catheter in a stable position relative to a target tissue, and components to irrigate the target tissue. In one embodiment, the ablation catheter 10 and the guiding catheter 50 are configured to permit the ablation catheter 10 to be inserted and removed from the guiding catheter 50. In another embodiment, the ablation catheter 10 and guiding catheter 50 are configured such that the ablation catheter 10 is not removable or separable from the guiding catheter 50.

The methods described herein include, in one embodiment, inserting the guiding catheter 50 into a body cavity and advancing the guiding catheter 50 to a location near an epicardial ablation target site. The guiding catheter 50 may be inserted via known methods, including minimally-invasive methods. In one embodiment, the guiding catheter 50 is inserted into the pericardial space via a percutaneous subxiphoid approach. The ablation catheter 10 is slidably disposed within the lumen 55 of the guiding catheter 50 and advanced until the distal portion 16 of the ablation catheter 10 exits the distal end 56 of the guiding catheter 50. In one embodiment, the distal portion 16 of the ablation catheter 10 is advanced about 5 cm to about 15 cm beyond the distal end 56 of the guiding catheter 50. Alternatively, the ablation catheter 10 and the guiding catheter 50 may be a single device such that the ablation catheter 10 is slidably disposed within the guiding catheter 50, but is not separable from the guiding catheter. In this embodiment, the guiding catheter 50 and ablation catheter 10 are inserted into a body cavity simultaneously and the distal portion 16 of the ablation catheter 10 may then be advanced or extended beyond the distal end 56 of the guiding catheter 50.

The ablating element 20 is then oriented to place the second surface 26 in contact with or facing the target tissue, for example an epicardial tissue. In one embodiment, the ablation catheter handle 18 is rotated or otherwise manipulated to cause axial rotation of the distal portion 16 of the ablation catheter 10. In other words, the distal portion 16 of the ablation catheter 10 rotates axially about a longitudinal axis of the

13

ablation catheter body **12**. EGM activity is sensed using the one or more electrodes **48** that are disposed on the distal portion **16** of the ablation device **10** near the ablating element **20**. When an EGM signal is sensed, the second surface of the ablating element is facing or contacting the epicardium. Thus, the practitioner continues to move or rotate the ablation catheter handle until an EGM signal is sensed, and optionally receives a signal indicating the orientation of the electrodes **48** and thus, the ablating element **20**.

Once the practitioner is confident that the second surface **26** is properly oriented in relation to the target tissue, a source of varying pressure, for example a vacuum pump, is activated to establish a region of low pressure near the second surface **26** of the ablating element **20** via the ports **30**. The region of low pressure maintains the ablating element **20** in a stable position and/or minimizes movement of the ablating element **20** relative to the target tissue. As noted previously, more than one ablating element **20** can couple to the distal portion **16** of the ablation catheter **10** and in that case one or more discrete low pressure regions can be implemented.

The methods further include delivering a fluid to the target tissue. The fluid, such as saline, hypertonic saline, water, refrigerant, contrast fluid, or the like, flows through the irrigation lumen to the irrigation channel surrounding the ablating element to irrigate or cool the tissue. In one embodiment, the temperature of the tissue is monitored via one or more temperature sensors **64**. The ablating element is then activated via a source of ablative energy to ablate the target tissue. In a further embodiment, the ablation catheter **10** is slowly withdrawn back through the guiding catheter **50** in a proximal direction while ablative energy is applied to the tissue to create a linear lesion. The vacuum pump may need to be temporarily shut-off or reduced to effect movement of the ablation catheter.

It is contemplated that, in one embodiment, the fluid does not enter the low pressure area where the tissue is stabilized. In other words, the vacuum pressure is sufficiently low to maintain a boundary of contact between the tissue being ablated and the fluid such that the fluid does not enter the ports **30** or the suction lumen **36**.

After ablating the tissue, the completeness of the ablation lesion can be confirmed using the one or more electrodes **48**. For example, in one embodiment, the electrodes **48** measure an impedance, as previously described herein. In a second embodiment, a first electrode may send a pacing signal across the lesion to determine if the lesion is complete. If a second electrode positioned on the opposite side of the ablating element **20** relative to the first electrode does not detect the pacing signal, or the signal is received relatively later than a pacing signal sent and received previously, the lesion can be considered relatively complete and free of ion-conducting inter-lesion gaps. Alternatively, the electrodes **48** may be used to measure impedance of the tissue between the electrodes **48** compared to a pre-ablation measurement.

EXAMPLE

The following example of methods of use is provided as additional disclosure although the specifics should be generally appreciated by those of skill in the art to which this disclosure pertains.

A method of ablating epicardial tissue includes providing a guiding catheter, the guiding catheter comprising a body and a continuous lumen extending through the body, a distal end, a proximal portion, and a first handle coupled to the proximal end, and providing an ablation catheter slidably disposed within the lumen of the guiding catheter. The ablation cath-

14

eter includes an elongate body defining a lumen therethrough, a proximal end, a second handle coupled to the proximal end, a distal portion, and at least one ablating element coupled to the distal portion. The at least one ablating element includes a first surface and a second surface, and the second surface includes a base portion, at least one port and a rim. The ablation catheter further includes at least one cardiac electrode coupled to the distal portion of the elongate body, a suction lumen coupled to the at least one port at a distal end thereof and a source of varying pressure at a proximal end thereof. Additionally, the ablation catheter includes an irrigation channel surrounding at least a portion of the rim, and an irrigation lumen fluidly coupled to the irrigation channel at a distal end thereof and a source of irrigation fluid at a proximal end thereof.

The method further includes inserting the guiding catheter and the ablation catheter into a body cavity, advancing the guiding catheter and the ablation catheter to a location near an epicardial tissue, and advancing the ablation catheter through the guiding catheter until the ablating element exits the distal end of the guiding catheter. The step of inserting a guiding catheter and the ablation catheter into a body cavity may include inserting the guiding catheter into the pericardial space via a percutaneous subxiphoid approach. The ablating element is oriented to place the second surface in contact with or facing an epicardial tissue, and the source of varying pressure is activated to maintain the ablating element in a stable position relative to the tissue, or minimize relative movement of the ablating element relative to the tissue. A fluid is delivered through the irrigation lumen and the irrigation channel to irrigate the tissue, and the ablating element is activated to ablate the tissue. To orient the ablating element in relation to the tissue, the second handle is manipulated to cause axial rotation of the distal portion of the ablation catheter relative to a longitudinal axis of the elongate ablation catheter body, and the at least one pair of electrodes sense electrical activity on the tissue to indicate when the ablating element is oriented towards the epicardial tissue. The at least one pair of electrodes may measure an impedance after ablating the tissue to confirm that an effective lesion has been created.

Another aspect of the disclosure, which is well-suited for use in connection with ultrasound ablation applications, is illustrated as tissue ablation apparatus **100** in FIG. **16**. Tissue ablation apparatus **100** includes a body **102** (which may be an extension of elongate body **12** described above). Extending through body **102** are a first, or vacuum, lumen **104** and a second, or irrigation, lumen **106** extending therethrough. As shown in FIG. **16**, first and second lumens **104** and **106** are separated from each other.

First lumen **104** may also connect to a third lumen **107**. One of ordinary skill in the art will appreciate that third lumen **107** is thus also a vacuum lumen. First lumen **104** has an interior cross-sectional area that is between about 10 to about 20 times greater than the interior cross-sectional area of third lumen **107**, with a relationship of about 17:1 being particularly desirable.

An ultrasound ablation element **108** is positioned within a distal region of body **102**. As generally known in the art, ultrasound ablation element includes an ultrasound transducer **110** and a membrane **112**. Membrane **112** extends over at least a portion of transducer **110**, thereby defining a cavity **114** between membrane **112** and transducer **110**. Second lumen **106** is in fluid communication with cavity **114** so as to allow a fluid (e.g., normal saline) to flow from a fluid supply (not shown), through second lumen **106**, and into cavity **114** to both cool transducer **110** and facilitate the delivery of

15

ultrasonic energy to adjacent tissue. This connection is referred to herein as a “fluid pathway.”

Tissue ablation apparatus **100** further includes dual suction ports, one on either side (e.g., distal and proximal) of ultrasound ablation element **108**. Thus, body **102** includes a first orifice **116** proximal to ultrasound ablation element **108** and a second orifice **118** distal to ultrasound ablation element **108**. First orifice **116** opens to first lumen **104** to define a first vacuum (or suction) pathway. Similarly, second orifice **118** opens to third lumen **107** (and thus, as shown in FIG. **16**, to first lumen **104**) to define a second vacuum (or suction) pathway. The second vacuum pathway further includes a distal vacuum chamber **119**, generally defined as the space between the end of third lumen **107** and second orifice **118**.

One of ordinary skill in the art will appreciate that, in the configuration shown in FIG. **16**, suction in the second vacuum pathway (i.e., the pathway formed by distal vacuum chamber **119**, third lumen **107**, and first lumen **104**) is subordinate to and dependent upon suction in the first vacuum pathway (i.e., the pathway formed by first lumen **104** alone). That is, if the first vacuum pathway is not sealed against tissue, there will be little or no suction through the second vacuum pathway.

Similarly, if the second vacuum pathway is not sealed against tissue, suction through the first vacuum pathway will be reduced. To address this concern, and thus to facilitate sufficient suction for stability against tissue even if the second vacuum pathway is not sealed against tissue, tissue ablation apparatus **100** further includes at least one flow control apparatus positioned to regulate flow through the second vacuum pathway independent of flow through the first vacuum pathway. That is, the flow control apparatus regulates flow through the second vacuum pathway, but not the first vacuum pathway. Thus, in some embodiments, the flow control apparatus is positioned at the distal end of third lumen **107**, i.e., at the junction **120** between third lumen **107** and second distal vacuum chamber **119** so as to regulate flow through the second (i.e., more distal) vacuum pathway. Of course, it is within the spirit and scope of the present teachings to provide flow regulation through both vacuum pathways, provided the pathways remain separately regulated (e.g., a first flow control apparatus regulates flow through the first vacuum pathway only, while a second flow control apparatus regulates flow through the second vacuum pathway only). Likewise, the flow control apparatus can be positioned anywhere along third lumen **107**, or even beyond the distal end of third lumen **107** (e.g., adjacent second orifice **118** within distal vacuum chamber **119**), and still provide regulation of flow only through the second vacuum pathway.

For the sake of illustration, three suitable flow control apparatuses are depicted in FIGS. **17A-17C**. FIG. **17A** depicts a mesh screen, which is referred to herein as a “passive flow regulating apparatus.” As used herein, the term “passive flow regulating apparatus” refers to any apparatus that obstructs flow without moving parts, such as tortuous pathways, weirs, screens, shunts, blocks, and the like.

In contrast, FIGS. **17B** and **17C** depict “active” flow regulating apparatuses—that is, apparatuses that obstruct or restrict flow via the use of moving parts. The term “iris” is used herein to describe an active flow apparatus that varies the effective size (e.g., diameter) of its opening, such as by mechanical, electronic, or other control (e.g., via fluid pressure). Thus, the duckbill valve shown in FIG. **17B** and the inflatable balloon mechanical iris depicted in FIG. **17C** are active flow control apparatuses that may be employed to good advantage in tissue ablation apparatus **100**. Other active flow control apparatuses include, without limitation, checkvalves,

16

waterwheels (e.g., rotor-type, backshot-type, and breastshot-type), and mechanical shutters.

Where an iris is used, it may be desirable to provide for user control of the effective size of the iris by mechanically linking the iris to a suitable actuator at the proximal end of body **12** (e.g., into handle **58**). The term “mechanically linked” is used herein to describe an actual physical linkage between the iris and the actuator therefor. One example of such a link is a pull wire coupled to a mechanical shutter that can be used to open and close the iris. Of course, other configurations are contemplated as well.

It is also desirable to regulate the flow of irrigation/cooling/acoustic coupling fluid through the fluid pathway. Accordingly, tissue ablation apparatus **100** may also include a fluid flow control apparatus positioned to regulate fluid flow through an outlet **122** of the fluid pathway. FIG. **16** depicts the outlet as opening into the distal vacuum chamber **119**; thus, it is contemplated that the fluid flow control apparatus may be positioned at the junction between the fluid pathway and the second vacuum pathway. It should be understood, however, that the fluid flow control apparatus may be placed anywhere along the fluid pathway to control flow therethrough. Suitable fluid flow control apparatuses are generally similar to the flow control apparatuses described above in connection with the vacuum pathways.

There are advantages associated with a fluid pathway that discharges into distal vacuum chamber **119**. For example, any air that is in cavity **114** is more easily purged. Likewise, the suction also facilitates elimination of bubbles. Another advantage is that irrigation/cooling/acoustic coupling fluid discharged into distal vacuum chamber **119** can be more easily scavenged without any adverse effects due to fluid pooling in the pericardial space.

Of course, there is a balance required between fluid flow through the fluid pathway and suction/vacuum applied to the second vacuum pathway in order to ensure that **114** remains under positive pressure. Thus, it is contemplated to provide a pressure sensor in the fluid pathway, the output of which can be monitored and considered when adjusting fluid flow and/or vacuum flow, either automatically or manually.

Proper fluid pressure can also be maintained by properly sizing the inlet and outlet of the fluid flow control apparatus. For example, it has been determined that the cross-sectional area of the inlet should be about 4 to about 20 times greater than the cross-sectional area of the outlet in order to maintain proper fluid pressure within cavity **114**.

The recitation of one or more embodiments discussed or described herein does not imply that other embodiments are not useful and is not intended to exclude other embodiments from the scope of the invention and no disclaimer of other embodiments should be inferred from the discussion of a certain embodiment or a figure showing a certain embodiment.

Although several embodiments of this invention have been described above with a certain degree of particularity, those skilled in the art could make numerous alterations to the disclosed embodiments without departing from the spirit or scope of this invention. For example, one of ordinary skill in the art will appreciate that the features and aspects disclosed above can be combined in various combinations, not all of which are explicitly described, without departing from the contemplation of the present teachings.

For example, FIG. **16** depicts the first and second vacuum pathways as connected and co-dependent. It is contemplated, however, that, in certain aspects, the first and second vacuum pathways may also be isolated from one another, for example via the use of dedicated lines and/or a manifold or source

17

outside of tissue ablation apparatus 100. This would allow suction in the first and second vacuum pathways to be essentially independent of each other (i.e., a loss of vacuum in one of the vacuum pathways has little or no effect on the suction in the other vacuum pathway).

All directional references (e.g., upper, lower, upward, downward, left, right, leftward, rightward, top, bottom, above, below, vertical, horizontal, clockwise, and counter-clockwise) are only used for identification purposes to aid the reader's understanding of the present invention, and do not create limitations, particularly as to the position, orientation, or use of the invention. Joinder references (e.g., attached, coupled, connected, and the like) are to be construed broadly and may include intermediate members between a connection of elements and relative movement between elements. As such, joinder references do not necessarily infer that two elements are directly connected and in fixed relation to each other.

It is intended that all matter contained in the above description or shown in the accompanying drawings shall be interpreted as illustrative only and not limiting. Changes in detail or structure may be made without departing from the spirit of the invention as defined in the appended claims.

What is claimed is:

1. A tissue ablation catheter comprising:
an elongate catheter body with a central longitudinal axis, the catheter body having at least a first lumen and a second lumen extending longitudinally through the catheter body, wherein the elongate catheter body is deflectable;
an ultrasound ablation element positioned within a distal region of the elongate catheter body, the ultrasound ablation element comprising:
an ultrasound transducer; and
a membrane extending over at least a portion of the ultrasound transducer, thereby defining a cavity between the membrane and the ultrasound transducer, wherein the second lumen is coupled to the cavity to define a fluid pathway;
a first orifice in the elongate catheter body proximal of the ultrasound ablation element and open to the first lumen to define a first vacuum pathway;
a distal vacuum chamber defined by the elongate catheter body distal of the ultrasound ablation element and in communication with the first lumen to define a second vacuum pathway;
a second orifice in the elongate catheter body distal of the ultrasound ablation element and open to the distal vacuum chamber; and
at least one flow control apparatus positioned to regulate flow through one of the vacuum pathways independent of flow through the other vacuum pathway.
2. The tissue ablation catheter according to claim 1, further comprising a third lumen coupled to the first lumen, wherein the third lumen is in communication with the distal vacuum chamber, and wherein the second vacuum pathway includes the third lumen.
3. The tissue ablation catheter according to claim 2, wherein an interior cross-sectional area of the first lumen is about 10 to about 20 times greater than an interior cross-sectional area of the third lumen.
4. The tissue ablation catheter according to claim 1, wherein the at least one flow control apparatus comprises:
a first flow control apparatus positioned to regulate flow through the first vacuum pathway independent of flow through the second vacuum pathway; and

18

a second flow control apparatus positioned to regulate flow through the second vacuum pathway independent of flow through the first vacuum pathway.

5. The tissue ablation catheter according to claim 1, wherein the fluid pathway comprises an outlet, and wherein the outlet of the fluid pathway opens into the second vacuum pathway.

6. The tissue ablation catheter according to claim 5, further comprising a fluid flow control apparatus positioned to regulate fluid flow through the outlet of the fluid pathway and into the second vacuum pathway.

7. The tissue ablation catheter according to claim 6, wherein the fluid flow control apparatus has an inlet and an outlet, and wherein the inlet of the fluid flow control apparatus has a cross-sectional area between about 4 and about 20 times greater than a cross-sectional area of the outlet of the fluid flow control apparatus.

8. The tissue ablation catheter according to claim 1, wherein the at least one flow control apparatus comprises an iris.

9. The tissue ablation catheter according to claim 8, further comprising an actuator coupled to the body and mechanically and operably linked to the iris in order to vary an effective size thereof.

10. The tissue ablation catheter according to claim 1, wherein the at least one flow control apparatus comprises a passive flow regulating apparatus.

11. A tissue ablation catheter comprising:

an elongate catheter body having a central longitudinal axis, the elongate catheter body having at least a first lumen and a second lumen extending through the catheter body, wherein the catheter body is deflectable;

an ultrasound ablation element positioned within a distal region of the elongate catheter body, the ultrasound ablation element comprising:

an ultrasound transducer; and

a membrane extending over at least a portion of the ultrasound transducer, thereby defining a cavity between the membrane and the ultrasound transducer, wherein the second lumen is coupled to the cavity to define a fluid pathway;

a first orifice in the elongate catheter body proximal of the ultrasound ablation element and open to the first lumen to define a first vacuum pathway;

a second orifice in the elongate catheter body distal of the ultrasound ablation element and open to the first lumen to define a second vacuum pathway,

wherein the fluid pathway is coupled to the second vacuum pathway;

a flow control apparatus positioned to regulate flow through the second vacuum pathway independent of flow through the first vacuum pathway; and

a fluid flow control apparatus positioned to regulate flow through the fluid pathway into the second vacuum pathway.

12. The tissue ablation catheter according to claim 11, wherein the fluid flow control apparatus is positioned at a junction between the fluid pathway and the second vacuum pathway.

13. The tissue ablation catheter according to claim 11, wherein the flow control apparatus is positioned at a distal end of the first lumen.

14. The tissue ablation catheter according to claim 11, wherein at least one of the fluid flow control apparatus and the flow control apparatus comprises an iris.

19

15. The tissue ablation catheter according to claim 14, further comprising an actuator coupled to the elongate body and mechanically and operably linked to the iris to adjust an effective size thereof.

16. The tissue ablation catheter according to claim 11, wherein at least one of the fluid flow control apparatus and the flow control apparatus comprises a passive flow regulating apparatus.

17. A tissue ablation catheter comprising:

an elongate tubular body having a central longitudinal axis, the elongate tubular body having a proximal end and a distal region, wherein the elongate tubular body is deflectable;

a vacuum lumen extending through the elongate tubular body from the proximal end to the distal region;

an irrigation lumen extending through the elongate tubular body from the proximal end to the distal region;

an ultrasound ablation element positioned within the distal region of the elongate tubular body, the ultrasound ablation element comprising:

an ultrasound transducer; and

a membrane extending over at least a portion of the ultrasound transducer, thereby defining a cavity between the membrane and the ultrasound transducer, wherein the irrigation lumen discharges into the cavity;

a first vacuum orifice through the elongate tubular body into the vacuum lumen proximal of the ultrasound ablation element;

20

a second vacuum orifice through the elongate tubular body into the vacuum lumen distal of the ultrasound ablation element,

a fluid discharge orifice in communication with the cavity and proximate a junction between the second vacuum orifice and the vacuum lumen; and

at least one means for controlling a flow through one of the first vacuum orifice, the second vacuum orifice, and the fluid discharge orifice independent of others of the first vacuum orifice, the second vacuum orifice, and the fluid discharge orifice.

18. The tissue ablation catheter according to claim 17, wherein the at least one means for controlling a flow comprises: a first means for controlling a flow through one of the first and second vacuum orifices independent of the other of the first and second vacuum orifices and the fluid discharge orifice; and a second means for controlling a flow through the fluid discharge orifice independent of flow through the first and second vacuum orifices.

19. The tissue ablation catheter according to claim 17, wherein the at least one means for controlling a flow comprises a passive means for controlling a flow.

20. The tissue ablation catheter according to claim 17, wherein the at least one means for controlling a flow comprises an active means for controlling a flow.

* * * * *